

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

**[Docket No. 2005N-0413]**

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DDM

**Assessing Consumer Perceptions of Health Claims; Public Meeting; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Assessing Consumer Perceptions of Health Claims." The meeting will present research assessing consumers' reactions to health claims and will address the implications of these studies for future research designed to evaluate consumer understanding of health claims and the effect of health claims on consumer perceptions and behaviors.

**DATES:** The public meeting will be held on Thursday, November 17, 2005, from 9 a.m. to 4:30 p.m. All of those attending the meeting must register by November 10, 2005. See section III of this document for details on how to register. Submit written or electronic comments, including all relevant data and information, related to the focus of the public meeting by January 17, 2006.

**ADDRESSES:** The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Harley W. Wiley Auditorium, 5100 Paint Branch Pkwy., College Park, MD 20740.

You may submit comments, identified by Docket No. 2005N-0413, by any of the following methods:

### *Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:  
Division of Dockets Management (HFA–305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

*Instructions:* All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and

insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*For general questions about the meeting, to register, to request permission to speak at the meeting, or to request onsite parking:* Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1584, FAX: 301-436-2371, e-mail: *marion.allen@fda.hhs.gov*.

*For technical questions:* Steven L. Bradbard, Center for Food Safety and Applied Nutrition (HFS-727), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1826, FAX: 301-436-1826, e-mail: *steve.bradbard@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Health claims are statements used on food labels or in food labeling that describe a relationship between a food or component of food and reduction in the risk of a disease or health-related condition (21 U.S.C. 343(r)(1)(B); § 101.14(a)(1) and (a)(2) (21 CFR 101.14(a)(1) and (a)(2)). The 1993 regulations for health claims (§ 101.14) adopted the congressionally mandated standard of significant scientific agreement (SSA) in the Nutrition Labeling and Education Act of 1990 (Public Law 101-538). This standard limits authorized health claims in food labeling to those dietary substance/disease relationships where, based on the totality of publicly available scientific evidence, there is significant scientific agreement among qualified experts that the claim is supported by such evidence. However, the approach of deciding whether a

claim was misleading or not based on FDA's evaluation of whether the scientific evidence met the significant scientific agreement standard was overturned in court on first amendment grounds (see *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (Pearson decision)).

The Pearson decision rejected FDA's approach in part because the agency did not meet its burden under the First Amendment of justifying a restriction on health claims that do not meet the SSA standard. The court criticized FDA's approach for not considering the possibility that disclaimers about the quality of science underlying claims that did not meet the SSA standard ("qualified health claims") could remedy any potential harm. Following the Pearson decision and subsequent related cases, including *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) (finding a "credible evidence" standard as the appropriate standard for FDA to apply in evaluating qualified health claims), FDA revised its process for reviewing qualified health claim petitions. FDA considers the use of qualified health claims when such claims are supported by credible scientific evidence and accurately communicate the level of scientific support for the claim. FDA instituted an interim system for communicating qualified health claims in food and dietary supplement labeling based on a four level system to classify health claim petitions in terms of the strength of science supporting the claim ("Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" (68 FR 41387, July 11, 2003); "Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (68 FR 41387)). At the same time it instituted this interim system, FDA developed a consumer studies research agenda designed to identify the most effective ways to best present scientifically based,

truthful and nonmisleading information to consumers and to identify the kinds of information known to be misleading to consumers. See “Consumer Studies Research Agenda—Improving Consumer Understanding and Product Competition on the Health Consequences of Dietary Choices,” Attachment D to the Report of the FDA Task Force on Consumer Health Information for Better Nutrition (July 10, 2003), available at <http://www.cfsan.fda.gov/~dms/nuttftoc.html#memo> (last accessed September 30, 2005).

FDA (Ref. 1) and others (Refs. 2 and 3) have conducted research to assess consumers’ responses to health claims. Some of this research has studied consumers’ reactions to qualifying language that is similar to that found in FDA’s interim system for communicating the level of scientific support for health claims. This research provides important information about consumers’ judgments about the level of scientific support for health claims, and reports the effects of health claims on consumers’ perceptions of the substance-disease relationship, product healthfulness, product quality and safety, and purchase intent.

## **II. Purpose and Scope of the Meeting**

FDA is holding this public meeting to discuss the findings from its own and other research that examines consumers’ reactions to health claims, including those claims supported by SSA and those that are qualified, on conventional foods and dietary supplements. The meeting also will allow attendees an opportunity to provide comments to FDA about the implications of the available research for further consumer studies that may be needed or that are already underway by other parties to assess consumer understanding of health claims and the effect of health claims on consumer perceptions and behaviors. FDA is also interested in hearing from commenters their views

regarding schemes or signals, other than those already studied, that may, consistent with the first amendment, effectively communicate to consumers the level of scientific support for health claims, without leading consumers to make erroneous inferences about the claimed substance-disease relationship and/or other product characteristics. FDA anticipates that this meeting will also include comments from attendees about alternative research methods to empirically assess consumer understanding of health claims and the effect of health claims on consumer perceptions and behaviors. FDA intends to consider all pertinent information from this public meeting in any rulemaking related to alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements (see 68 FR 66040, November 25, 2003).

### **III. Registration**

Please submit your registration information (including name, title, firm name (if applicable), address, telephone, FAX (if available), by November 10, 2005. We encourage you to register online at <http://www.cfsan.fda.gov/~comm/register.html> or by FAX to Marion V. Allen at 301-436-2605. Space is limited and registration will be closed when maximum seating capacity is reached. Please also specify whether you need onsite parking when you register. We also will accept registrations onsite, if space is available.

If you need special accommodations due to a disability, please contact Marion V. Allen (see **FOR FURTHER INFORMATION CONTACT**) no later than November 10, 2005.

If you wish to make a presentation, indicate your request when registering and submit the following information by November 10, 2005: (1) A brief written statement about the general nature of the views you wish to present

and (2) the names of any copresenters who must also register to attend. The amount of time allowed for each oral presentation at the public meeting will be limited (e.g., 5 minutes each), and will depend in part upon the number of persons who request to speak. Individuals and organizations that do not preregister to make a presentation may be given an opportunity to speak if time permits.

Persons preregistered or wishing to register onsite should check in between 7:30 and 8:30 a.m. Because the meeting will be held in a Federal building, meeting participants must present photo identification and plan adequate time to pass through the security system.

#### **IV. Comments**

In addition to attending or presenting oral comments at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to the focus of this public meeting. All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### **V. Meeting Transcript**

A transcript will be made of the meeting's proceedings. You may request a copy in writing from FDA's Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 30 working days after the public meeting at a cost of 10 cents per page. The transcript of public meeting and all comments

submitted will be available for public examination at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

## **VI. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be viewed between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Derby, B.M. and A.S. Levy, "Working Paper: Effects of Strength of Science Disclaimers on the Communication Impact of Health Claims," Working Paper No. 1, FDA, Center for Food Safety and Applied Nutrition (<http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>), September 2005.

2. France, K.R. and P.F. Bone, "Policy Maker's Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels," *Journal of Consumer Affairs*, Volume 39, No. 1, Copyright 2005 by the American Council on Consumer Interests, 2005.

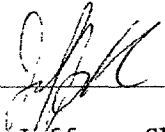


3. Qualified Health Claims Consumer Research Project Executive Summary,  
International Food Information Council Foundation (<http://www.ific.org/research/qualhealthclaimsres.cfm>), March 2005.

Dated: \_\_\_\_\_

10/14/05

October 14, 2005.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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